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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/739,089	12/15/2000	Constantinos Balas	FRN-002	3243

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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

NERBUN, PETER P

ART UNIT	PAPER NUMBER
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3765

DATE MAILED: 01/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/739,089

Applicant(s)

BALAS, CONSTANTINOS

Examiner

Peter P Nerbun

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 10.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8. 6) ☐ Other:

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The drawings filed on December 15, 2000 are objected because the acronyms "NAT" and "NATC" appear to be misplaced. On page 14, lines 8-10 of the specification applicant refers to a "curve" ATC and a "curve" NATC. Figure 1 of the drawings illustrates two straight lines (not curves) that are labeled "NAT" and "NATC". Clarification of this matter is required.

The specification is objected to for containing minor errors in sentence structure. In particular, on page 14, line 7, "illustrated: pixel" should be changed to --illustrated each representing a--; on page 14, line 26, "using" should be changed to --Using--; on page 15, line 1, "comprise" should be changed to --comprises--; on page 15, lines 10 and 24, "of the remitted" should be changed to --remitted--.

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet as set forth in 37 CFR 1.78(a)(2) and (a)(5)). Applicant claims the benefit of a U.S. provisional application pursuant to 35 USC 119(e), however applicant does not provide a specific reference to a prior application since the reference given by applicant does not identify the application number of the U.S. provisional Application entitled "Method and Apparatus for Amplifying Pathological Features in Tissues", filed on December 15, 1999. Applicant further claims the benefit of this provisional application on page 3 of the declaration, filed August 30, 2001. The same deficiency noted above is present in this declaration. Thus the present declaration filed August 30, 2001 is objected to and new declaration is required that provides the application serial

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number of the provisional application that is partially identified in the present declaration. Note that 37 CFR 1.78 (a)(4) states that in order for a nonprovisional application to claim the benefit of one or more prior filed provisional applications, each prior provisional application must name as an inventor at least one inventor named in the later filed nonprovisional application and disclose the named inventor's invention claimed in at least one claim of the later filed nonprovisional application in the manner provided by the first paragraph of 35 U.S.C. 112. In a paper entitled "Letter Regarding Rights of Priority under 35 USC 119(e), a statement is made that the provisional application entitled "Method and Apparatus for Amplifying Pathological Features in Tissues", filed on December 15, 1999 disclosed an embodiment of the invention solely invented by the applicant of the instant application. Further that letter states that the applicant of the instant application was not listed as an inventor in the provisional application and that the filer of the provisional application "has acknowledged that the above-identified Applicant is an inventor of a disclosed embodiment and an appropriate remedy is being sought". In this regard note that 37 CFR 1.48(d) states that "If the name or names of an inventor or inventors were omitted in a provisional application through error without any deceptive intention on the part of the omitted inventor or inventors, the provisional application may be amended to add the name or names of the omitted inventor or inventors. Amendment of the inventorship requires:

- (1) A request, signed by a party set forth in § 1.33(b), to correct the inventorship that identifies the inventor or inventors being added and states that the inventorship error occurred without deceptive intention on the part of

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the omitted inventor or inventors; and

(2) The processing fee set forth in § 1.17(q).

Further 37 CFR 1.48(e) states that "If a person or persons were named as an inventor or inventors in a provisional application through error without any deceptive intention on the part of such person or persons, an amendment may be filed in the provisional application deleting the name or names of the person or persons who were erroneously named. Amendment of the inventorship requires: (1) A request to correct the inventorship that sets forth the desired inventorship change; (2) A statement by the person or persons whose name or names are being deleted that the inventorship error occurred without deceptive intention on the part of such person or persons; (3) The processing fee set forth in § 1.17(q); and (4) If an assignment has been executed by any of the original named inventors, the written consent of the assignee (see § 3.73(b) of this chapter)." Since applicant has not met the requirements set forth in 37 CFR 1.78 (a)(4), 37 CFR 1.48(d) and 37 CFR 1.48(e), applicant may not claim the benefit of a U.S. provisional application pursuant to 35 USC 119(e). Should applicant file papers which meet the requirements set forth in 37 CFR 1.78 (a)(4), 37 CFR 1.48(d) and 37 CFR 1.48(e), applicant then may claim the benefit of the U.S. provisional application pursuant to 35 USC 119(e).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Kaufman et al (U.S. Patent Application Publication No. US 2002/0127735 A1), cited on the PTO-1449, filed December 2, 2002 (paper no. 8). The patent application publication to Kaufman et al discloses a method for monitoring the effects of a pathology differentiating agent on a tissue sample, comprising: applying a pathology differentiating agent (see page 1, lines 3-6 of paragraph [0006]), wherein said pathology differentiating agent chemically interacts with said tissue sample and alters its optical characteristics; and monitoring the rate of change of light reflection from said tissue sample over time (see page 6, paragraph [0072] and page 11, paragraph [0114]), thereby monitoring the effects of a pathology agent on a tissue sample.

Claims 6, 7, 9-13 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Richards-Kortum et al, newly cited. The patent to Richards-Kortum discloses a method for the *in vivo* diagnosis of a tissue abnormality in a subject comprising contacting a tissue in a subject with a pathology differentiating agent (see col. 2, lines 44-46), wherein said pathology differentiating agent chemically interacts with said tissue sample and alters its optical characteristics (see col. 2, lines 47-48), exposing said tissue in said subject to optical radiation (see col. 1, lines 47-48), and monitoring the intensity of light emitted from said

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tissue over time (see col. 1, lines 48-53 and 60-61 and col. 2, lines 49-50), thereby diagnosing a tissue abnormality in a subject (see col. 1, lines 62-67). Richards-Kortum uses acetic acid as the pathology differentiating agent (see col. 2, lines 41-43). The high resolution imaging disclosed by Richards-Kortum can be used to obtain near real-time reflected light images of the tissue being examined. Since Richards-Kortum discloses that multiple images are being obtained, the monitoring of the intensity of light emitted from the tissue in Richards-Kortum is being done "over time".

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Richards-Kortum et al in view of Zavislan, newly cited. To utilize polarized optical radiation in the method of Richards-Kortum as suggested by Zavislan (at col. 2, lines 18-20) would have been obvious since Zavislan states this technique results in a reduction in the amount of surface reflection.

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richards-Kortum et al. The particular type of tissue to which the tissue may be exposed (ear, esophagus, etc.) could have been selected in an obvious manner since Richards-Kortum et al state that their method applies to

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multiple tissue types and should be useful for improving contrast in a variety of organ sites (see col. 4, lines 36-41).

The declaration filed on December 2, 2002 under 37 CFR 1.131 has been considered but is ineffective to overcome the Kauffman references (U.S. Patent Application Publication No. US 2002/0127735 A1 and U.S. Patent Application Publication No. US 20020007122 A1). The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Kauffman references (U.S. Patent Application Publication No. US 2002/0127735 A1 and U.S. Patent Application Publication No. US 20020007122 A1). While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). Applicant presents an article received and accepted by the Journal of Photochemistry and Photobiology as evidence to establish conception of the invention prior to the effective date of the Kauffman references. This article does not describe the step of monitoring the rate of change of light reflection from a tissue sample over time, thereby monitoring the effects of a pathology differentiating agent on the tissue sample, as disclosed by applicant on page 6, lines 29-31 of the instant application.

With regard to the declaration filed on December 2, 2002 under 37 CFR 1.131, the evidence submitted is insufficient to establish diligence from a

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date prior to the date of reduction to practice of the Kauffman reference to either a constructive reduction to practice or an actual reduction to practice. Where conception occurs prior to the date of the reference, but reduction to practice is afterward, it is not enough merely to allege that applicant or patent owner had been diligent. *Ex parte Hunter*, 1889 C.D. 218, 49 O.G. 733 (Comm'r Pat. 1889). Rather, applicant must show evidence of facts establishing diligence. The record must set forth an explanation or excuse for the inactivity; the USPTO or courts will not speculate on possible explanations for delay or inactivity. See *In re Nelson*, 420 F.2d 1079, 164 USPQ 458 (CCPA 1970).

The declaration filed under 37 CFR 1.132 filed December 2, 2002 is noted. 37 CFR 1.132 states that "When any claim of an application or a patent under reexamination is rejected or objected to, any evidence submitted to traverse the rejection or objection on a basis not otherwise provided for must be by way of an oath or declaration under this section.". The declaration filed by applicant is not directed to the traverse of a rejection made in the last mailed Office action (paper no. 6). Rather applicant states that he is the co-author of a paper and that the other co-authors are not co-inventors of the subject matter described and claimed in the instant application. Thus it would appear that the declaration was not filed properly under 37 CFR 1.132. Notwithstanding the above, it is noted that a declaration filed pursuant to 37 CFR 1.132 must be supported by evidence. Applicant offers only opinion testimony on the ultimate legal conclusion at issue (viz. that the co-authors are not co-inventors of the

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subject matter disclosed in the instant application). Such opinion as to a legal conclusion is not entitled to any weight.

Applicant's arguments filed December 6, 2002 and December 17, 2002 have been fully considered. Applicant states that "the claims presented herein essentially correspond to the claims of U.S. Publication Number US 2002/0127735 A1 and U.S. Patent Application Publication Number US 20020007122 A1. ". The examiner disagrees with this conclusion since claim 1 of U.S. Publication Number US 2002/0127735 A1 recites "dispensing a plurality of chemical agents on a tissue, wherein the chemical agents interact to alter an optical signal produced by the tissue". Applicant's claim 1 merely recites applying a pathology differentiating agent on a tissue sample, wherein said pathology differentiating agent chemically interacts with said tissue sample and alters its optical characteristics". Applicant's claim 1 says nothing about dispensing a plurality of chemical agents on a tissue *wherein the chemical agents interact* (emphasis added) as claimed by U.S. Publication Number US 2002/0127735 A1. Indeed applicant lacks disclosure to support such a claim. The same comments apply to U.S. Patent Application Publication Number US 20020007122 A1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter P Nerbun whose telephone number is 703-308-0955. The examiner can normally be reached on M-F (1st Week) M-Th (2d Week).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John J Calvert can be reached on 703-305-1025. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0758 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0861.

Peter Nerbun
January 5, 2003

A handwritten signature in black ink that reads "Peter Nerbun". The signature is fluid and cursive, with the first letter of each word being capitalized and prominent.

Peter Nerbun
Primary Examiner